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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,133	07/23/2003	Joseph M. Starobin	9159-4	8270

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EXAMINER	
JACKSON, BRYAN M	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,133	STAROBIN ET AL.	
	Examiner	Art Unit	
	Bryan M. Jackson	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7/23/03.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 30 July 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/15/03, 12/23/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The Information disclosure statement (IDS) submitted on 12/15/03 and 12/23/04 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 and 17-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Starobin (6361503). Starobin discloses a "method of assessing cardiac ischemia in a subject to provide a measure of cardiovascular health in said subject during stimulation in said subject, said method comprising the steps of: (a) collecting a first QT- and RR-interval data set from said subject during a stage of gradually increasing heart rate; (b) collecting a second QT- and RR-interval data set from said subject during a stage of gradually decreasing heart rate, with said first and second QT- and RR-interval data sets being collected while minimizing the influence of rapid transients due to autonomic nervous system and hormonal control on said data sets; (c) comparing said first QT- and RR-interval data set to said second QT- and RR-interval data set to determine

the difference between said data sets; and (d) generating from said comparison of step (c) a measure of cardiac ischemia during stimulation in said subject, wherein a greater said difference between said first and second data sets indicates greater cardiac ischemia and lesser cardiovascular health in said subject" (claim 1), wherein significant difference between the amplitudes and time constants of the QT/RR interval gradual changes and abrupt heart rate fluctuations allows one to average these fluctuations over time and fit the QT/RR protocol duration dynamics by an appropriate smooth exponential-like function with a high order of accuracy (col 17/18, ln 66/16), processing "RR-interval data set to produce two sufficiently smooth curves" including the ascending and descending heart rate branches (fig 4B, step 44b), the stage of gradually increasing exercise load (or increased average heart rate) and the stage of gradually decreasing exercise load (or decreased average heart rate) are preferably carried out sequentially in time--that is, with one stage following after the other substantially immediately, without an intervening rest stage. In the alternative, the two stages may be carried out separately in time, with an intervening "plateau" stage" (col 10, ln 55-60), "collecting said first and second QT- and RR-interval data sets under quasi-stationary conditions" (claim 2), "stage of gradually increasing heart rate and said stage of gradually decreasing heart rate are each at least 3 minutes in duration" (claim 3), "stage of gradually increasing heart rate and said stage of gradually decreasing heart rate are together carried out for a total time of from 6 minutes to 40 minutes" (claim 4), "both said stage of gradually increasing heart rate and said stage of gradually

decreasing heart rate are carried out between a peak rate and a minimum rate; and said peak rates of both said stage of gradually increasing heart rate and said stage of gradually decreasing heart rate are the same" (claim 5), "minimum rates of both said stage of gradually increasing heart rate and said stage of gradually decreasing heart rate are substantially the same" (claim 6), "gradually decreasing said heart rate at least three different heart-rate stimulation levels" (claim 7), "gradually increasing said heart rate at least three different heart-rate stimulation levels" (claim 8), "gradually increasing said heart rate and gradually decreasing said heart rate sequentially in time" (claim 9), "gradually increasing said heart rate and gradually decreasing said heart rate separately in time" (claim 10), "said generating step is carried out by generating curves from each of said data sets" (claim 11), "said generating step is carried out by comparing the shapes of said curves from said data sets" (claim 12), "said generating step is carried out by determining a measure of a domain between said curves" (claim 13), "said generating step is carried out by both comparing the shapes of said curves from said data sets and determining a measure of a domain between said curves" (claim 14), "step of displaying said curves" (claim 15), "said heart rate during said stage of gradually increasing heart rate does not exceed more than 120 beats per minute" (claim 16), "said heart rate during said stage of gradually increasing heart rate exceeds 120 beats per minute" (claim 17), "step 46a, 46b performed by the application part of the software can be graphically presented as closing the two branch hysteresis loop with an appropriate line, such as a vertical straight line or a line connecting the initial and final points, in order to produce a closed

hysteresis loop on the (T.sub.QT,T.sub.RR)-plane" (col 13, ln 46-51), "step 47a, 47b the application software evaluates for each ECG lead an appropriate measure of the domain inside the closed hysteresis loop" (col 13, ln 52-54), "cardiovascular health of an individual can be quantitatively evaluated, compared and monitored" (col 3, ln 48-49), "assess the efficacy of the cardiovascular therapy or the progress of the subject", wherein a "decrease in the difference between said data sets from before said therapy to after said therapy, or over time, indicates an improvement in cardiac health in said subject from said cardiovascular therapy" (col 12, ln 39-44), and "suitable cardiovascular therapy can be administered, including but not limited to aerobic exercise, muscle strength building, change in diet, nutritional supplement, weight loss, smoking cessation, stress reduction, pharmaceutical treatment (including gene therapy), surgical treatment (including both open heart and closed heart procedures such as bypass, balloon angioplasty, catheter ablation, etc.) and combinations thereof" (col 12, ln 44-51).

Regarding claims 1-2 and 24-37, it is noted that averaging RR-interval fluctuations over time and fitting RR-intervals by an appropriate smooth exponential-like function is a result of separating fluctuations for RR-interval data sets from a trend which would allow for the comparison of said fluctuations for RR-interval data sets from a trend.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Starobin in view of Deno (20040049235). Starobin discloses the claimed invention except for the monitoring of pulse or blood pressure. Deno teaches that it is known to use fluctuations in absolute blood pressure with respect to R-waves (fig 1) to provide RR-interval data sets collected by blood pressure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the RR-interval data sets as taught by Starobin, with monitoring blood pressure with respect to R-waves as taught by Deno, since such a modification would provide the RR-interval data sets with monitoring of blood pressure with respect to R-waves for providing the RR-interval data sets via the monitoring of blood pressure.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mulligan (20050027323) discloses an implantable medical device for monitoring cardiac blood pressure and chamber dimension. Stadler (6128526) discloses a method for ischemia detection and apparatus for using same. Joo (6171256) discloses a method and apparatus for detecting a condition associated with acute cardiac ischemia. Medema (6217525) discloses a reduced lead set device and method for detecting acute cardiac ischemic conditions. Lu (20020072777/6604000) discloses a method and device for

responding to the detection of ischemia in cardiac tissue and a method and device for responding to the detection of ischemia in cardiac tissue, respectively. Sheldon (20030158492) discloses ischemia detection. Bayer (6532381) discloses a patient monitor for determining a probability that a patient has acute cardiac ischemia. Stahmann (20040133247) discloses a method for ischemia detection by implantable cardiac device. Condie (20030045908) discloses an implantable medical device (IMD) system configurable to subject a patient to a stress test and to detect myocardial ischemia within the patient. Kroll (6865420) discloses a cardiac stimulation device for optimizing cardiac output with myocardial ischemia protection. Obel (5199428) discloses an implantable electrical nerve stimulator/pacemaker with ischemia for decreasing cardiac workload. Noren (5676690) discloses an apparatus for administering medical therapy using detrended fluctuation analysis of physiological activity

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryan M. Jackson whose telephone number is 571-272-7335. The examiner can normally be reached on Monday through Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GEORGE R. EVANISKO
PRIMARY EXAMINER
1/5/6